

REMARKS

1. Inventorship

The inventorship designation of the instant application has been amended herein pursuant to 37 C.F.R. §1.48(b) by deleting the name of Kumar Visvanathan. In compliance with 37 C.F.R. 1.48(b), this amendment is accompanied by a Petition which includes a statement identifying each named inventor who is being deleted and acknowledging that the deleted inventor's invention is no longer being claimed in the application. Also in compliance with 37 C.F.R. 1.48(b), the Fee of \$130.00 for the Petition, as set forth in 37 C.F.R. § 1.17(i), is provided for.

2. Sequence Listing

The specification has been amended to include a sequence listing containing nucleotide and amino acid sequences referred to elsewhere in the specification. As suggested in the attachment to the Office Action, submitted herewith are pages 40 to 51 of the sequence listing containing the sequences from parent application 08/838,413, filed April 7, 1997, and a Letter Requesting Transfer of Computer Readable Form of Sequence Listing from parent application 08/838,413, filed April 7, 1997. The letter contains a statement pursuant to 37 C.F.R. § 1.821 (f) or 1.825(b) or (d) that the paper sequence listing and the computer readable form containing the sequence listing submitted herewith are identical.

3. Claims

Claims 4 to 6, 8 and 11 to 49 are deleted herein without prejudice. Applicants note that the subject matter of claims 4 to 6, 8 and 11 to 12 was allowed in parent application 08/838,413 filed April 7, 1997, and issued in US Patent 6,075,119 on June 13, 2000. New claims 50 to 59 have been added herein. After entry of the amendment, claims 1-3, 7, 9 to 10, and 50 to 59 will

be pending.

New claims 50 to 54 are directed to a peptide of SEQ. ID NO: 30, with various selections for the variable amino acids. Support for these claims is found on page 23, lines 1 to 7 of the specification (in the section concerning consensus sequence #1b).

New claim 55 is directed to a peptide of any one of claims 50 to 54 wherein the amino acid sequence is a component of a larger molecule which is retained after dialysis to remove molecules with molecular weights of less than 6000-8000 daltons. Support for this claim is found, e.g., on page 23, last line, to page 24, line 7; page 28, lines 20 to 24; and page 43, lines 16 to 18 of the specification, wherein it is stated that "The polymerized molecules were then dialyzed to remove molecules with molecular weights less than 6000-8000 daltons."

New claims 56 and 57 are directed to a pharmaceutical composition comprising a peptide of any one of claims 50 to 54, or 55, respectively. Support for pharmaceutical compositions comprising the peptides of the invention is found throughout the specification. See, e.g., page 10, lines 28 to 30; page 12, lines 6 to 9; and page 35, line 9 of the specification.

New claims 58 to 59 are directed to a method of inducing serum antibodies that bind at least one staphylococcal enterotoxin or streptococcal exotoxin, comprising administering a peptide of any one of claims 50 to 54, or 55, respectively. Support for methods of inducing antibodies which bind staphylococcal enterotoxin or streptococcal exotoxin is found throughout the specification. See, e.g., page 34, line 25 to page 35, line 4; page 46, lines 16 to 25; and Figure 5 of the specification.

4. The Restriction Requirement

The Examiner has restricted the claims into 14 groups as follows:

- I. Claims 1-6, drawn to a peptide, classified in class 530, subclass 350.
- II. Claims 7 and 8, drawn to a pharmaceutical composition, classified in class 424, subclass 237.1.
- III. Claims 9-13 and 24, drawn to a method of inducing serum antibodies that bind at least one enterotoxin or exotoxin, administering a peptide, classified in class 424, subclass 184.1.
- IV. Claims 14-16 and 24, drawn to a method of inducing serum antibodies which detect toxins, classified in class 424, subclass 184.1.
- V. Claims 17-19 and 24, drawn to a method of inducing serum antibodies which inhibit blastogenesis of human mononuclear cells, administering an antibody, classified in class 424, subclass 184.1, 165.1+.
- VI. Claims 20-24, drawn to a method of passive immunization, classified in class 530, subclass 387.1, 388.1; class 424, subclass 130.1+.
- VII. Claims 25-29, drawn to nucleic acids, classified in class 536, subclass 23.1.
- VIII. Claims 30 and 31, drawn to methods of inducing serum antibodies that bind enterotoxin or endotoxin, administering nucleic acids, classified in class 514, subclass 45.
- IX. Claim 32, drawn to antibodies, classified in class 530, subclass 388.1, 387.1.
- X. Claim 33, drawn to methods for detecting the presence of a toxin using an antibody, classified in class 435, subclass 7.2, 7.33, 7.34.
- XI. Claims 34 and 35, drawn to methods for detecting the presence of antibodies to staphylococcus or streptococcal toxins using a peptide, classified in class 436, subclass 518, 7.2, 7.33, 7.34.
- XII. Claims 36-38, drawn to kits, classified in class 435, subclass 975.
- XIII. Claims 39-44 and 49, drawn to a method of inhibiting blastogenesis of human mononuclear cells, administering peptides, classified in class 424, subclass 184.1.
- XIV. Claims 45-49, drawn to a method of protecting a mammal, administering a peptide, classified in class 424, subclass 234.1, 237.1; class 514, subclass 12.

The examiner has requested that Applicants elect a group of claims to be examined. The examiner has also requested that Applicants elect a single species (i.e., a single specific sequence)

for prosecution on the merits if no generic claim is held allowable. Applicants are also requested to identify the claims which read upon that species.

In response to the restriction/election requirement made by the Examiner, Applicants elect Group I, claims 1 to 6. However, Applicants respectfully request that the Examiner also examine claims 7 to 13 (of Groups II and III), which are drawn to compositions and a method of inducing serum antibodies, in this group, as was done in parent application 08/838,413 filed April 7, 1997, which had the same claims 1-38. In that application, the Examiner indicated that the peptides, compositions and methods of those claims were classified in class 530, subclass 350. Applicants respectfully submit that searching these groups together would not be a serious burden on the Examiner as required by M.P.E.P. §803 if restriction is not required. Applicants respectfully request that the claims of Groups II and III, as well as new claims 50 to 59, be included in Group I and/or examined together with the claims of Group I identified by the Examiner.

As requested by the Examiner, Applicants elect the peptides CMYGGVTEHEGN of new claim 54 as the species for prosecution on the merits if no generic claim is held allowable. Claim 54 is directed to a peptide comprising a consensus amino acid sequence CMYGGX₁TX₂HX₄GN (SEQ ID NO: 30) wherein X₁ is V; X₂ is selected from the group consisting of E or L; and X₄ is E. In other words, claim 54 is directed to a peptide comprising the amino acid CMYGGVTEHEGN or CMYGGVTLHEGN. The peptides of claim 54 differ only at position X₄ (i.e., position 8 of the 13 amino acid sequence). Applicants traverse the requirement by the Examiner of the election of only a single species for prosecution on the merits if no generic claim is held allowable. Applicants respectfully submit that searching the specific peptide sequences of claim 54 (i.e., a total of two specific peptide sequences), would not be a serious burden on the

Examiner. Applicants respectfully point out to the Examiner that as stated in M.P.E.P. §803.04 entitled "Restriction-Nucleotide Sequences", that even though nucleotide sequences encoding different proteins are normally considered to constitute independent and distinct inventions, and would be subject to a Restriction Requirement Under 37 CFR §1.141, the Commissioner has decided to partially waive the requirements of 37 CFR §1.141 *et seq.* and allow, in most cases, up to ten (10) independent sequences to be claimed in a single application. Therefore, Applicants respectfully request that peptides comprising the amino acid sequence CMYGGVTLHEGN of claim 54 be examined in this application together with the elected peptides comprising the amino acid sequence CMYGGVTEHEGN.

Out of the pending elected claims of Group I, i.e., claims 1 to 3 (and 7, 9 and 10, if rejoined with the claims of Group I), and newly added claims 50-59, claims 1, 2, 7, 9, 10, and 50 to 59 read upon the elected peptide of claim 54 (i.e., CMYGGVTEHEGN). Claims 1, 2, 3, 7, 9, 10, and 50 to 59 read upon the other peptide of claim 54 (i.e., CMYGGVTLHEGN).

Applicants note that the Examiner has indicated that, upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. Applicants also note that the Examiner has indicated that SEQ ID NO: 28 (re: consensus region 1) is considered to be generic.

CONCLUSION

Applicants have elected the claims of Group I for action on the merits, have requested that the claims of Group II and III be joined with the claims of Group I, and have added new claims 50 to 59, which Applicants have requested be examined together with the claims of Group I. Applicants have also elected the peptides of claim 54 (i.e., peptides comprising the amino acid

CMYGGVTEHEGN or CMYGGVTLHEGN), but specifically CMYGGVTEHEGN, if one species needs to be elected, as the species to be examined on the merits if no generic claim is held allowable.

Applicants have also provided a copy of the Sequence Listing from the parent application application 08/838,413, filed April 7, 1997 and a Letter Requesting Transfer of Computer Readable Form of Sequence Listing from parent application 08/838,413, filed April 7, 1997, with the required statement concerning identity.

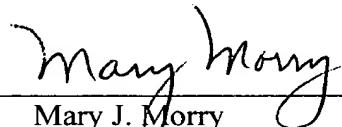
Applicants have also provided a Petition to Correct Inventorship, with appropriate fee.

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendment and an action passing this case to issue is therefore respectfully requested.

In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

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By 
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